



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0961]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review--Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0322. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Environmental Impact Considerations

This information collection helps support implementation of the National Environmental Policy Act (NEPA), consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act. All applications or petitions requesting FDA action require the submission of an environmental assessment (EA) or a claim of categorical exclusion (CE). A CE applies to Agency actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or environmental impact statement (EIS). Regulations in part 25 (21 CFR part 25) set forth FDA procedures with regard to NEPA requirements (part 25, subpart A); identify actions that require the preparation of an EA (part 25, subpart B); explain CEs (part 25, subpart C); and discuss the preparation of documents (part 25, subpart D). The regulations also supplement procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" (45 FR 76519 to 76534, November 19, 1980).

In the *Federal Register* of August 25, 2021 (86 FR 47501), we published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited. On our own initiative and for efficiency of Agency operations, we are revising the information collection to account for burden that may result from recommendations found in Agency guidance and currently approved in OMB control number 0910-0541. The guidance document entitled, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" identifies, interprets, and clarifies existing requirements imposed by applicable statutes and regulations, consistent with the CEQ regulations (40 CFR 1507.3). It consists of recommendations that do not themselves create requirements; rather, they are explanatory guidance for FDA's own procedures in order to ensure

full compliance with the purposes and provisions of NEPA. The guidance document is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-preparing-claim-categorical-exclusion-or-environmental-assessment-submission-cfsan>, and was issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR part 25; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section 25.40(c); actions excluded from the requirement to prepare EA or EIS:					
Center for Drug Evaluation and Research (CDER)	14	0.9285	13	3,400	44,200
Center for Devices and Radiological Health (CDRH)	0	-	0	-	0
Center for Biologics Evaluation and Research (CBER)	4	1	4	3,400	13,600
Center for Veterinary Medicine (CVM)	9	1	9	2,160	19,440
Center for Tobacco Products (CTP)	14	1	14	80	1,120
Center for Food Safety and Applied Nutrition (CFSAN)	57	1	57	180	10,260
Subtotal			97		88,620
Section 25.15(d); actions subject to CE:					
CDER	5,186	4.2273	21,923	8	175,384
CDRH	62	1	62	6	372
CBER	3,575	2	7,150	8	57,200
CVM	114	10	1,140	2,160	3,420
CTP	0	-	0	-	0
CFSAN	51	1	51	8	408
Subtotal			30,326		236,784
Total			30,423		325,404

¹ There are no capital, or operational and maintenance costs associated with the information collection.

CDER:

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for CE under § 25.30 or § 25.31, or an EA under § 25.40.

CDRH:

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for CE under § 25.30 or § 25.34 or an EA under § 25.40.

CBER:

Under 21 CFR 601.2(a), biologic license applications (BLAs) as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of CE under § 25.30 or § 25.32 or an EA under § 25.40.

CVM:

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications and generic investigational new animal drug applications, and 21 CFR 571.1(c) food additive petitions must contain a claim for CE under § 25.30 or § 25.32 or an EA under § 25.40.

CTP:

Under sections 905, 910, and 911 of the FD&C Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalences (SEs), exemption from SEs, and modified risk tobacco product applications must contain a claim for a CE or an EA. Upon evaluation, we have concluded that the majority of the EA burden for tobacco products is accounted for in other information collections currently approved by OMB. The burden we attribute to SEs is currently approved in OMB control number 0910-0673; the burden we attribute to PMTAs is currently approved in OMB control number 0910-0768; and the burden we attribute to SE exemptions is currently approved in OMB control number 0910-0684.

CFSAN:

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

As a result of revising the information collection to include submissions made to CFSAN, it reflects an increase in burden of 108 responses and 10,668 hours annually.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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